IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC. and ORION CORP., Plaintiffs, v. EUROHEALTH INTERNATIONAL SARL and WEST-WARD PHARMACEUTICAL CORP., Defendants.	C.A. No. 14-487-GMS PUBLIC REDACTED VERSION FILED MAY 10, 2016
HOSPIRA INC. and ORION CORP., Plaintiffs, v. EUROHEALTH INTERNATIONAL SARL and WEST-WARD PHARMACEUTICAL CORP., Defendants.	C.A. No. 14-1008-GMS PUBLIC REDACTED VERSION FILED MAY 10, 2016

EXHIBIT A TO PROPOSED JOINT PRETRIAL ORDER

John M. Seaman (#3868)
Sarah E. Hickie (#5833)
ABRAMS & BAYLISS LLP
20 Montchanin Road, Suite 200
Wilmington, DE 19807
Tel: (302) 778-1000
Fax: (302) 778-1001
seaman@abramsbayliss.com
hickie@abramsbayliss.com

Karen E. Keller (#4489)
Jeffrey T. Castellano (#4837)
David M. Fry (#5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298 0700
kkeller@shawkeller.com
jcastellano@shawkeller.com
dfry@shawkeller.com

OF COUNSEL:

Thomas J. Meloro
Heather M. Schneider
Erin E. McLeod
Dan Constantinescu
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019
Telephone: (212) 728-8000
tmeloro@willkie.com
hschneider@willkie.com
dconstantinescu@willkie.com

Attorneys for Plaintiffs Hospira, Inc. and Orion Corporation

OF COUNSEL:

William G. James
GOODWIN PROCTER LLP
901 New York Ave., NW
Washington, DC 20001
(202) 346-4000
WJames@goodwinprocter.com

Cynthia Lambert Hardman
Brian J. Prew
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 459-7199
CHardman@goodwinprocter.com
BPrew@goodwinprocter.com

Samuel Sherry
Jenny J. Zhang
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000
SSherry@goodwinprocter.com
JZhang@goodwinprocter.com

Attorneys for Defendants Eurohealth International SARL and West-Ward Pharmaceutical Corp.

Dated: May 2, 2016

EXHIBIT A

EXHIBIT A

Hospira, Inc., et al. v. Eurohealth International Sarl, et al.,
Case Nos. 1:14-cv-00487-GMS and 1:14-cv-01008-GMS (D. Del.)

Statement of Uncontested Facts

I. The Parties

1. Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

2. Orion is a corporation organized under the laws of Finland with its principal place of business at Orionintie lA, FI-02200 Espoo, Finland.

3. Eurohealth is a company organized and existing under the laws of Switzerland with a place of business at Rue Des Battoirs 7, Genève, Genève 1205, Switzerland.

4. West-Ward is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

5. Eurohealth has agreed to be substituted for Ben Venue Laboratories, Inc. ("BVL") as Defendant in this action.

6. Effective July 15, 2014, BVL divested itself of all rights, title, and interest in and to ANDA Nos. 205046 and 206407. Eurohealth now owns ANDA Nos. 205046 and 206407 and has informed the Food and Drug Administration ("FDA") of its commitment to all agreements, promises, and conditions made by the former owner and contained therein. For the purposes of the present action, Eurohealth assumes full responsibility and liability for BVL's actions relating to ANDA Nos. 205046 and 206407 and the subject matter contained therein.

7. West-Ward has been appointed as Eurohealth's agent in the United States for ANDA Nos. 205046 and 206407.

II. Deadline Under 21 U.S.C. 355(j)

8. ANDA No. 205046 is not subject to a thirty month stay. (D.I. 3, No. 14-487.)

9. The thirty month stay with respect to ANDA No. 206407 expires on December 20, 2016. (D.I. 21, No. 14-1008.)

III. The Patent-in-Suit

10. The '867 patent is entitled "Use of Dexmedetomidine for ICU Sedation" and was issued by the United States Patent and Trademark Office on April 6, 2004. The named inventors of the '867 patent are Riku Aantaa, Romeo Bachand, and Esa Heinonen.

11. Hospira and Orion are co-assignees of the '867 patent and share ownership of the '867 patent.

12. Hospira is a licensee in the United States of Orion's ownership interest in the '867 patent.

13. The '867 patent is listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") with respect to Plaintiffs' PRECEDEX™ drug product.

14. According to the Orange Book, the '867 patent and its associated pediatric exclusivity will expire on October 1, 2019.

IV. Prior Litigation

15. The '867 patent has previously been the subject of litigation between Plaintiffs and Sandoz before the U.S. District Court for the District of New Jersey. (D.I. 63 at ¶¶ 43-45, No. 14-487.)

16. The U.S. District Court for the District of New Jersey issued an opinion concluding that the claims of the '867 patent are obvious under 35 U.S.C. § 103 in view of the

prior art, including the 1995 publication by Dr. P. Talke et al., titled "Effects of Perioperative Dexmedetomidine Infusion in Patients Undergoing Vascular Surgery" ("Talke 1995") and the 1992 publication by Dr. Aho et al., titled "Dexmedetomidine Infusion for Maintenance of Anesthesia in Patients Undergoing Abdominal Hysterectomy" ("Aho V"). *Hospira Inc. et al. v. Sandoz Inc. et al*., 2012 WL 1587688, at *30-31 (D.N.J. May 4, 2012).

17. In that opinion, the District Court for the District of New Jersey found that claims 1 to 5 of the '867 patent were not anticipated pursuant to 35 U.S.C. § 102 by Talke 1995. *See Hospira Inc. et al. v. Sandoz Inc. et al*., 2012 WL 1587688, at *20 (D.N.J. May 4, 2012).

18. Subsequent to the issuance of the May 4, 2012, Opinion, Plaintiffs, Sandoz, Inc., and Sandoz Canada moved pursuant to Federal Rule of Civil Procedure 60(b) to vacate parts of the May 4, 2012, Opinion and the May 4, 2012, Order and Judgment relating to the '867 patent. (D.I. 43 at ¶ 45, No. 14-487).

19. In, *Hospira, Inc. v. Sandoz Inc*., 2014 U.S. Dist. LEXIS 25072 (D.N.J. February 27, 2014), along with a corresponding order and judgment, the U.S. District Court for the District of New Jersey vacated the parts of the May 4, 2012, Opinion and the May 4, 2012, Order and Judgment that pertain to the invalidity of the '867 patent. (D.I. 43 at ¶ 45, No. 14-487.)

20. In an order denying Defendants' letter request for leave to file a summary judgment motion on the issue of collateral estoppel (D.I. 33, No. 14-487), this Court stated: "Judge Cooper's intention in granting the motion to vacate is clear, and the court will not second-guess the policy considerations that drove her decision." (D.I. 44 at 2, No. 14-487.) This Court noted that "Judge Cooper's 'order expunge[d] the findings of fact and conclusions of law.'" (*Id.*, quoting *Sentinel Trust Co. v. Universal Bonding Insurance Co.*, 316 F.3d 213, 222 (3d Cir. 2003).) This Court also stated: "A judgment that has been vacated, reversed, or set aside

on appeal is thereby deprived of all conclusive effect, both as res judicata and as collateral estoppel." (*Id.* quoting (*Stolt-Nielsen, S.A. v. United States*, 442 F.3d 177, 187 n.7 (3d Cir. 2006).)

V. Plaintiffs' PRECEDEX™ Drug Product

21. Hospira is the holder of New Drug Application ("NDA") No. 21-038, for dexmedetomidine hydrochloride injection, sold in the United States under the trademark PRECEDEX™.

22. The United States Food and Drug Administration ("FDA") originally approved NDA No. 21-038 on December 17, 1999.

23. Precedex is sold as a concentrated version that requires dilution before use (100 mcg/mL in a 200 mcg/ml vial) and as a ready-to-use premix version that does not require dilution before use (400 mcg/100 mL, 200 mcg/50mL, and 80 mcg/20 mL containers).

24. As originally approved, PRECEDEX™ was indicated for "[s]edation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting."

25. In October 2008, Hospira obtained FDA approval for a second indication, specifically "Sedation of non-intubated patients prior to and/or during surgical and other procedures."

26. Plaintiffs are asserting claims 1 to 12 of the '867 patent against Defendants. Claim 1 of the '867 patent reads: "[a] method of sedating a patient in an intensive care unit, which comprises administering to the patient an effective amount of dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the patient remains arousable and orientated."

CONTAINS INFORMATION DESIGNATED "CONFIDENTIAL" PURSUANT TO PROTECTIVE ORDER

VI. Defendants' Proposed ANDA Products

27. On December 20, 2012, Bedford Laboratories submitted ANDA No. 205046, for dexmedetomidine hydrochloride concentrate (200 mcg/2mL), with a Paragraph IV Certification as to the '867 patent.

28. [redacted]

29. BVL sent a letter dated September 6, 2013 notifying Plaintiffs that BVL had filed ANDA No. 205046 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to market a dexmedetomidine hydrochloride concentrate drug product prior to the expiry of the '867 patent.

30. On December 26, 2013, Bedford Laboratories submitted ANDA No. 206407, for dexmedetomidine hydrochloride ready-to-use (400 mcg/100 mL and 200 mcg/50 mL), with a Paragraph IV Certification as to the '867 patent.

31. [redacted]

32. BVL sent a letter dated June 17, 2014, notifying Plaintiffs that BVL had filed ANDA No. 206407 with the FDA under section 505(j) of the FDCA, seeking approval to market a dexmedetomidine hydrochloride ready-to-use drug product prior to the expiry of the '867 patent.

33. On August 1, 2014 Bedford Laboratories sent letters notifying the FDA that, effective July 15, 2014, all rights in ANDAs No. 205046 and 206407 had been transferred to Eurohealth and West-Ward.

34. [redacted]

35. [redacted]

VII. Claim Construction

36. The parties agreed on the following constructions:

a. "effective amount" means "an amount sufficient to produce the desired effect."

b. "patient" means "human or animal patient."

c. "remains" means "continues to be."

d. "intensive care unit" means "any setting that provides care to critically ill patients, typically characterized by high nurse-to-patient ratios, continuous medical supervision, and intensive monitoring."

e. "sedating a patient in an intensive care unit" means "rendering a patient calm and managing patient comfort in any setting that provides care to critically ill patients, typically characterized by

high nurse-to-patient ratios, continuous medical supervision, and intensive monitoring."

f. "arousable and orientated" means "capable of being awakened, aware of one's environment, and able to interact with others."

37. The Court construed the following claim terms:

a. "dexmedetomidine" means "substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt."

b. "loading dose" means "dose administered at the onset of therapy to achieve a target concentration."

c. "maintenance dose" means "dose given as a continuous infusion to maintain a target concentration or desired effect."